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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/845,717	05/02/2001	Soren Nielsen	NIELSEN=3B	3818

7590 07/21/2004

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EXAMINER	
DEBERRY, REGINA M	

ART UNIT	PAPER NUMBER
1647	

DATE MAILED: 07/21/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/845,717	NIELSEN ET AL.	
	Examiner	Art Unit	
	Regina M. DeBerry	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 April 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,4,5,11 and 13-17* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,4,5,11 and 13-17* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

In view of the Petition to Vacate Restriction Requirement and Subsequent Office Action filed 26 April 2004, the restriction requirement (02 October 2003) and Non-Final Office Action (25 February 2004) are vacated, thereby rendering Applicant's election filed 02 December 2003 moot. The restriction has been re-formulated as follows.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1, 2, 5, 17, drawn in part, to a method for treating/preventing a condition in the tissue of the organ of a mammal said condition caused by ischemia of the tissue comprising administering a pharmaceutically effective dose of alpha-MSH and/or alpha-MSH equivalent and EPO and/or EPO equivalent to the mammal in need thereof, classified in class 514, subclass 2.

II. Claims 1, 2, 4, 5, 13, drawn in part, to a method for treating/preventing a condition in the tissue of the organ of a mammal, said condition caused by coronary artery disease, comprising administering a pharmaceutically effective dose of alpha-MSH and/or alpha-MSH equivalent and EPO and/or EPO equivalent to the mammal in need thereof, classified in class 514, subclass 2.

III. Claim 11, drawn to a pharmaceutical composition comprising a combination of alpha-MSH or and/or alpha-MSH equivalent and EPO and/or EPO equivalent together with a pharmaceutically acceptable carrier, classified in class 530, subclass 350.

IV. Claims 1, 2, 5, 14, drawn in part, to a method for treating/preventing a condition in the tissue of the organ of a mammal, said condition caused by atheromatous disease with thrombosis, embolism, aortic aneurysm, allergic reaction comprising administering a pharmaceutically effective dose of alpha-MSH and/or alpha-MSH equivalent and EPO and/or EPO to the mammal in need thereof, classified in class 514, subclass 2.

V. Claims 1, 2, 5, 15, drawn in part, to a method for treating/preventing a condition in the tissue of the organ of a mammal, said condition caused by ischemia secondary to a condition or disease comprising administering a pharmaceutically effective dose of alpha-MSH and/or alpha-MSH equivalent and EPO and/or EPO equivalent to the mammal in need thereof, classified in class 514, subclass 2.

VI. Claims 1, 2, 5, 16, drawn in part, to a method for treating/preventing a condition in the tissue of the organ of a mammal, said condition caused by surgery, transplantation, surgical insertion transplants, devices, grafts, prostheses or other biomedical compounds or devices comprising administering a pharmaceutically effective dose of alpha-MSH and/or

alpha-MSH equivalent and EPO and/or EPO equivalent to the mammal in need thereof, classified in class 514, subclass 2.

Inventions I, II, IV-VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). The instant Groups are directed to methods that recite structurally and functionally distinct elements, are not required one for the other, and/or achieve different goals.

Invention I requires treating/preventing a condition caused by ischemia of the tissue, which is not required or accomplished by the method steps of the other Groups. Invention II requires treating/preventing a condition caused by coronary artery disease, which is not required or accomplished by the method steps of the other Groups. Invention IV requires treating/preventing a condition caused by atheromatous disease with thrombosis, embolism, aortic aneurysm, allergic reaction, which is not required or accomplished by the method steps of other Groups. Invention V requires treating/preventing a condition caused by ischemia secondary to a condition or disease, which is not required or accomplished by the method steps of other Groups. Invention VI requires treating/preventing a condition caused by surgery, transplantation, surgical insertion transplants, devices, grafts, prostheses or other biomedical compounds

or devices, which is not required or accomplished by the method steps of other Groups.

The instant Groups are directed to methods that encompass treating different patient populations. The Groups require search and consideration of diverse diseases, conditions and techniques, which may not overlap. For example coronary artery disease exhibits a different pathology versus diabetes mellitus. A search on graft transplants would not necessarily overlap with hypotension. Therefore, a search and examination of the methods in one patent application would result in an undue burden, since the searches for the methods are not co-extensive, the classification is different, and/or the subject matter is divergent.

Inventions III and I, II, IV-VI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product of Group III can be used in process to make antibodies. Furthermore, the process of Groups I, II, IV-VI can all be practiced with a different product.

The Examiner has required restriction between product and process claims. Where Applicant elects claims directed to the product, and a product claim is subsequently found

allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims.

Failure to do so may result in a loss of the right to rejoinder. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where

the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

In addition:

Claim 2 is generic to a plurality of disclosed patentably distinct species comprising different organs. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

Claim 14 is generic to a plurality of disclosed patentably distinct species comprising different conditions. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

Claim 15 is generic to a plurality of disclosed patentably distinct species comprising different conditions. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

Claim 16 is generic to a plurality of disclosed patentably distinct species comprising different conditions. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, separate search requirements, and/or recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Regina M. DeBerry whose telephone number is (571) 272-0882. The examiner can normally be reached on 9:00 a.m.-6:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda G. Brumback can be reached on (571) 272-0961. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

RMD
6/13/04

ELIZABETH KEMMERER
PRIMARY EXAMINER